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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,693	01/29/2004	Shaw G. Fox	17050/1098007	5585

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EXAMINER

JUNG, UNSU

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 09/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/767,693	<b>Applicant(s)</b> FOX, SHAW G.	
	<b>Examiner</b> Unsu Jung	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2005.  
 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.  
     4a) Of the above claim(s) 22-26 is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 1-21 is/are rejected.  
 7) ☒ Claim(s) 4,6-9,17 and 20 is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.  
 10) ☒ The drawing(s) filed on 29 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/2904</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group I (claims 1-21) in the reply filed on August 8, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### ***Oath/Declaration***

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The clause regarding "willful false statements ..." required by 37 CFR 1.68 has been omitted.

### ***Specification***

3. The use of the trademark CLINITECK® (p2, line 25, p9, line 15), MULTISTIX® (p2, line 28, p9, line 8) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

***Claim Objections***

4. Claim 4 is objected to because of the following informalities: "a" is needed after the word "comprises" in line 2. Appropriate correction is required.
5. Claim 6 is objected to because of the following informalities: "a" is needed after the word "to" in line 3. Appropriate correction is required.
6. Claim 7 is objected to because of the following informalities: "an" is needed after the word "comprises" in line 2. Appropriate correction is required.
7. Claim 8 is objected to because of the following informalities: "a" is needed after the word "comprises" in line 2. Appropriate correction is required.
8. Claim 9 is objected to because of the following informalities: "a" is needed after the word "comprises" in lines 2 and 5. Appropriate correction is required.
9. Claim 17 is objected to because of the following informalities: a comma is needed after the word "conjugates" in line 5. Appropriate correction is required.
10. Claim 20 is objected to because of the following informalities: "a" is needed after the word "comprises" in line 1 and a comma is needed after the word "analytes" in line 2. Appropriate correction is required.

11. Claim 21 is objected to because of the following informalities: a comma is needed after the word "batch" in line 2. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1, 5, and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

14. Claim 1 recites the limitation "the surface" in line 7. There is insufficient antecedent basis for this limitation in the claim.

15. Claim 5 recites the limitation "the strength" in 1. There is insufficient antecedent basis for this limitation in the claim.

16. Claim 21 recites the limitation "the production batch" in line 2 and "the date" in line 3. There is insufficient antecedent basis for this limitation in the claim.

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***Claim Rejections - 35 USC § 103***

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

19. Claims 1-4, 10-12, 17, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howard (U.S. Patent No. 5,945,341, Filed Oct. 21, 1996) in view of Ruppender (U.S. Patent No. 4,510,383, Filed Aug. 31, 1982).

Howard teaches a test strip for analysis of one or more analytes in a fluid test sample comprising a carrier of an absorbent material (column 12, line 59) and a plurality of test fields on the surface of the carrier (column 3, lines 47-51 and column 12, line 60). The carrier exhibits light reflectance within a first predetermined spectral range (column 12, line 64-column 13, line 1) and the test fields including a plurality of test field materials reactive with one or more analytes exhibit light reflectances within a second

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predetermined spectral range (column 12, lines 60-63). The first and second predetermined spectral range being distinguishable from one another (column 12, line 64-column 13, line 1). Furthermore, Howard teaches marker fields, which have a capability to reflect light at different specific ranges of wavelengths from each other and correlate to information concerning identification of the test strip (column 12, line 64-column 13, line 5). However, Howard fails to teach the gaps and the test fields having relative sizes, which are optically discernable, wherein the relative sizes form a coded sequence that correlates to information relating to the test. By, design, the marker fields on the test strip will be limited to a finite number of colors or classifications based on the measurable reflectances (column 5, lines 28-30).

Ruppender teaches an optical identification of a coding, which consists of a distance between a code block and a first adjacent test field of a test strip (column 1, lines 13-18). Various types of strips differ by the distance (gap) between the code field and the first test field and this gap can be used as a coding for certain information (column 1, lines 23-25). On the surface of a test strip, there is provided a bar coding which consists of individual code bars, which vary in their breadth and in their distance (gap) apart (column 3, lines 13-15). Parts of carrier material not having any code bars represent gaps (column 3, lines 13-19 and Fig. 1). Therefore, the gaps have light reflectance within the first predetermined spectral range.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the color coding method using marker fields having a capability to reflect light at different specific ranges of wavelengths from each other as

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taught by Howard with another coding method, which uses varying distances between a code block and a first adjacent test field of a test strip as taught by Ruppender in order to provide an optical identification of the coding for an adjacent test field without any limitation by a finite number of colors or classifications based on the measurable reflectances. Thus, the plurality of test fields with an adjacent gaps used as a coding information provides the arrangement of plurality of test fields disposed in spaced relation to one another on a carrier, wherein the marker fields (gaps) between the test fields exhibit light reflectance within the first predetermined spectral range.

With respect to claim 3, Howard teaches a test strip, wherein the test fields comprise test pads (column 7, lines 35-48).

With respect to claim 4, Howard teaches a test strip, wherein the test fields configured to generated at least one response within a range of responses comprises reflectance within a predetermined spectral range (column 8, lines 55-60).

With respect to claim 10, Howard teaches a substrate comprising a carrier fabricated from an absorbent material (column 3, lines 47-50).

With respect to claim 11, Howard teaches a substrate is elongated, having a longitudinal axis (column 13, lines 6-7).

With respect to claim 12, Ruppender teaches gaps, which are elongated and extended substantially parallel to one another in a direction transverse to the longitudinal axis of the elongated substrate (Fig. 1).

With respect to claim 17, Howard teaches a substrate fabricated from a material which allows one or more analytes and labeled antibodies specific thereto to flow

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through it along with the fluid test sample and to form analyte/labeled antibody conjugates that can be captured in a specific capture zone of the test strip (column 13, lines 12-17).

With respect to claim 20, Howard teaches a test, wherein the information comprise identification of the one or more analytes, for which the test is designed to test (column 12, lines 47-49).

With respect to claim 21, Howard teaches a test, wherein the information comprises information relating to the production batch from which the test was obtained, and test strip age (column 1, lines 43-45 and lines 49-51). It would be obvious to one of ordinary skill in the art to realize that the test strip age would require a date of manufacture of the test strip.

20. Claim 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howard (U.S. Patent No. 5,945,341, Filed Oct. 21, 1996) in view of Ruppender (U.S. Patent No. 4,510,383, Filed Aug. 31, 1982) as applied to claim 2 above, and further in view of Kibrick (U.S. Patent No. 4,901,073, Filed Mar. 30, 1988).

Howard in view of Ruppender teaches a test strip as discussed above. Howard teaches marker fields, which have a capability to reflect light at different specific ranges of wavelengths from each other and correlate to information concerning identification of the test strip (column 12, line 64-column 13, line 5). Ruppender further teaches that various types of strips differ by the distance (gap) between the code field and the first test field and this gap can be used as a coding for certain information (column 1, lines

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23-25). However, Howard in view of Ruppender fails to teach a test strip, wherein the strength of a response generated by a test field is proportional to the relative size of the test field.

Kibrick teaches an optical encoding system with series of light reflecting wide rectangles and narrow rectangles alternating with dark (i.e. non-reflecting) wide rectangles and narrow rectangles. Kibrick further teaches that that strength (high or low) of signal corresponds to the spatial width of the space being scanned (column 17, lines 9-13 and Fig. 8).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to realize that the gaps having varying widths as taught by Howard in view of Ruppender would generate reflectance signals, which correspond to the spatial widths of the gaps, in order to use the gaps with different widths as a coding for certain information.

With respect to claims 6, 8, and 9, Howard teaches a use of marker fields, which have a capability to reflect light at different specific ranges of wavelengths from each other (column 12, line 64-column 13, line 5) and the specific ranges of wavelengths are predetermined (column 14, lines 26-31).

With respect to claim 7, Howard teaches a use of marker fields, which are black in color. It is well known in the art that black absorbs incident light (i.e. non-reflecting). Furthermore, according to Merriam-Webster Dictionary, the term "absorption band" is defined as a dark band in an absorption spectrum (p7, column 3). Therefore, it would

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be obvious to one of ordinary skill in the art to realize that the black marker field of Howard would absorb an incident light.

With respect to claim 8, Howard teaches an optical code consisting of marker fields capable of reflecting light at different specific ranges of wavelengths from each other and the specific ranges of wavelengths are predetermined (column 14, lines 26-31).

21. Claims 13-16, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howard (U.S. Patent No. 5,945,341, Filed Oct. 21, 1996) in view of Ruppender (U.S. Patent No. 4,510,383, Filed Aug. 31, 1982) as applied to claim 11 above, and further in view of Howard et al. (U.S. Patent No. 5,408,535, Filed Sept. 7, 1993).

Howard in view of Ruppender teaches a test strip as discussed above. Howard teaches marker fields, which have a capability to reflect light at different specific ranges of wavelengths from each other and correlate to information concerning identification of the test strip (column 12, line 64-column 13, line 5). Ruppender further teaches that various types of strips differ by the distance (gap) between the code field and the first test field and this gap can be used as a coding for certain information (column 1, lines 23-25). However, Howard in view of Ruppender fails to teach a test strip, wherein the coded sequence is defined by the relative width of test fields.

Howard et al. teaches a test strip reader, which does not require a test strip with a fixed test pad size and fixed spacing between test pad areas and can locate,

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determine physical extent of each color band and measure spectral reflectance within each color band (column 4, lines 25-27).

Therefore, it would have been obvious to one of ordinary skill in the art to include in the test strip of Howard in view of Ruppender with test pads (test fields) having different sizes and light reflecting capabilities as taught by Howard et al. in order to use light reflecting characteristics and different sizes as a coding for certain information concerning identification of the test strip.

With respect to claims 18 and 19, Howard et al. teaches a test strip comprising at least four test fields and gaps with optically discernable sizes (Fig. 3).

### ***Conclusion***

22. No claims allowed.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Unsu Jung whose telephone number is 571-272-8506. The examiner can normally be reached on M-F: 9-5.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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02/21/01